



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 106 and 107

[Docket No. FDA-1995-N-0063 (formerly 95N-0309)]

RIN 0910-AF27

Current Good Manufacturing Practices, Quality Control Procedures, Quality Factors,

Notification Requirements, and Records and Reports, for Infant Formula; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA or we) is correcting a final rule that appeared in the Federal Register of June 10, 2014. The final rule revised our infant formula regulations by establishing requirements for current good manufacturing practices, including audits; establishing requirements for quality factors; and amending our quality control procedures, notification, and record and reporting requirements for infant formula. We issued the final rule to provide greater protection of infants who consume infant formula products. In this document, we correct some errors that appeared in the preamble to the final rule.

DATES: Effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Leila Beker, Office of Nutrition, Labeling, and Dietary Supplements (HFS-850), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1451.

SUPPLEMENTARY INFORMATION: In FR Doc. 2014-13384, appearing on page 33057 in the Federal Register of June 10, 2014 (79 FR 33057), we make the following corrections:

1. On pages 33057-33058, under “FOR FURTHER INFORMATION CONTACT:,” the contact information is changed to read, “Leila Beker, Office of Nutrition, Labeling, and Dietary Supplements (HFS-850), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1451.”
2. On page 33062, in the third column, in Comment 9, “45 °F (F)” is corrected to read “45 °F.”
3. On page 33063, in the third column, in Comment 13, the preamble stated, “The comment requested that, with regard to the requirements of § 106.35, we announce the exercise of enforcement discretion or a formal delay for this provision to align with the compliance date for eligible infant formulas. Nonetheless, with the exception of the compliance date for certain requirements related to quality factors for eligible infant formulas, the final rule adopts a compliance date of September 8, 2014 to facilitate manufacturer compliance with all requirements of this final rule.” We are correcting this passage to read, “The comment requested that, with regard to the requirements of § 106.35, we announce the exercise of enforcement discretion, a delayed compliance date, or a formal delay for this provision to align with the compliance date for eligible infant formulas.”
4. On page 33063, in the third column, in the Response to Comment 13, the preamble stated, “We therefore decline the request to announce the exercise of enforcement discretion, a delayed compliance date, or a formal delay for this provision to align with the compliance date for eligible infant formulas.” We are correcting this passage to read, “We therefore decline the request to announce the exercise of enforcement

discretion or a formal delay for this provision to align with the compliance date for eligible infant formulas. Nonetheless, with the exception of the compliance date for certain requirements related to quality factors for eligible infant formulas, the final rule adopts a compliance date of September 8, 2014, to facilitate manufacturer compliance with all requirements of this final rule.”

Dated: July 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.